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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/485,951 02/17/00 KATO

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EXAMINER

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--------------------------------------|-----------------------------------|
| Application No. 09/485,951 | Applicant(s) Kato et al |
| Examiner Karen Canella | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6-14 is/are pending in the application. is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

Art Unit: 1642

DETAILED ACTION

1. Acknowledgment is made of applicants election, without traverse, of Group I, drawn to proteins comprising SEQ ID NO:1 and 2.
2. Claims 1-5 have been canceled. Claims 6-14 have been added. Claims 11-14, drawn to the invention of Group II, are withdrawn from consideration. Claims 6-10 are examined on the merits.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility.

The asserted utilities for the galectin-9 like protein (SEQ ID NO:2) are the use of said protein as a reagent for carbohydrate research (pg. 1, lines 8-10); therapeutic use, a tissue marker for undisclosed diseases, the production of antibodies , a biochemical reagent, identification of other proteins which bind to said protein (pg. 21-22) and as a nutritional source (pg. 23). These asserted utilities for galectin-9 like protein apply to many unrelated proteins. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to galectin-9 like protein of SEQ ID NO:2. Furthermore, the specification makes many speculative suggestions on the utility of the claimed SEQ ID NO:2 in inducing or inhibiting cell differentiation (pg. 23, line 20-23), stimulating or suppressing the immune system (pg. 26, lines 6-8), regulation of hematopoiesis and the treatment of myeloid or lymphoid cell deficiencies (pg. 35, lines 6-9), tissue repair and replacement (pg. 37, lines 13-18), inducing or inhibiting contraception or fertility (pg. 41, lines 10-26), exhibiting chemotactic or chemokinetic activity (pg. 42, lines 10-16), , exhibiting hemostatic or thrombolytic activity (pg. 43, lines 22-24), receptor, ligand or agonist activity (pg.

Art Unit: 1642

44, lines 13-16), exhibiting anti-inflammatory activity (pg. 16-17), and tumor inhibiting activity (pg. 46, lines 9-12).

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function beyond the binding of galactose or biological significance for galectin-9 like protein and in the absence of any further objective data, the utilities recited in the paragraph supra are prophetic. The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to other galectins, especially to galectin-9. The specification states on pg. 2, lines 3-6, that "the true role of galactin-9 has not yet been completely characterized." After further research, a specific and substantial credible utility might be found for the claimed SEQ ID NO:1 and 2. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to

Art Unit: 1642

be a broad field. . . . a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the galectin-9 like protein (SEQ ID NO:2) of the instant application was, as of the filing date, useful for inducing or inhibiting cell differentiation (pg. 23, line 20-23), stimulating or suppressing the immune system (pg. 26, lines 6-8), regulation of hematopoiesis and the treatment of myeloid or lymphoid cell deficiencies (pg. 35, lines 6-9), tissue repair and replacement (pg. 37, lines 13-18), inducing or inhibiting contraception or fertility (pg. 41, lines 10-26), exhibiting chemotactic or chemokinetic activity (pg. 42, lines 10-16), , exhibiting hemostatic or thrombolytic activity (pg. 43, lines 22-24), receptor, ligand or agonist activity (pg. 44, lines 13-16), exhibiting anti-inflammatory activity (pg. 16-17), and tumor inhibiting activity (pg. 46, lines 9-12). Further there is no art of record that would support the function of the galectin-9 itself in any of the utilities contemplated by the specification for the instant invention of galectin-9 like protein. Until some actual and specific significance can be attributed to the galectin-9 like protein, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

The DNA of the instant invention (SEQ ID NO:5) was isolated from a cDNA library of stomach cancer cells. Northern hybridization was carried out in order to determine the expression pattern of SEQ ID NO:5 in human tissues. The strongest expression was observed in the peripheral blood, with some expression in the heart, placenta, lung, spleen, thymus, ovary and large and small intestines. The specification teaches that this expression pattern is not similar to that of the known galectin-9 and therefore the protein of the instant invention is predicted to have a differing function from that of galectin-9. Furthermore, the specification does not teach a

Art Unit: 1642

relationship between the expression of SEQ ID NO:5 or lack thereof with any specific disease or establish any involvement of the galectin-9 like protein in the etiology of any specific disease or teach which fragments might be active or which derivatives would function in a pharmaceutical composition. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed galectin-9 like protein. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1642

(A) Claim 7 recites "wherein the fragment comprises at least 88 contiguous amino acids of SEQ ID NO:1". SEQ ID NO:1 consists of only 32 amino acids according to the Sequence Listing and the CRF.

(B) Claim 8 reads "nucleic acid molecule comprising SEQ ID NO:1 or 2", however, the Sequence Listing and the CRF identify SEQ ID NO:1 and 2 as polypeptides. For purpose of examination claim 8 will be read as --nucleic acid molecule encoding SEQ ID NO:1 or 2--.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

10. Claims 6, 7, 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Tuereci et al (Journal of Biological Chemistry, March 1997, Vol. 272, pp. 6416-6422). Claim 1 is drawn in part to a protein comprising SEQ ID NO:1. Claim 8 is drawn in part to a polypeptide consisting of an allelic variant of a polypeptide comprising SEQ ID NO:1 wherein the polynucleotide encoding said allelic variant hybridizes under stringent conditions to the nucleic acid molecule encoding SEQ ID NO:1. Claim 9 is drawn to a polypeptide which is at least 70% homologous to SEQ ID NO:1 or SEQ ID NO:2. Tuereci et al disclose a protein comprising the instant SEQ ID NO:1 which is therefore at least 70% homologous to SEQ ID NO:1, the nucleotides encoding said protein would hybridize under stringent conditions to the nucleotides encoding SEQ ID NO:1. Further, the protein disclosed by Tuereci et al is 98% homologous to the instant SEQ ID NO:2.

Art Unit: 1642

11. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Wada et al (Journal of Biological Chemistry, March 1997, Vol. 272, pp. 6078-6086). Wada et al disclose rat galectin-9 which is 71.7% homologous to SEQ ID NO:2.

12. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 6,027,916). Claim 9 is drawn in part to a polypeptide which is at least 70% homologous to SEQ ID NO:2. Ni et al disclose the polypeptide of SEQ ID NO:4 which is 85.2% homologous to the instant SEQ ID NO:2.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 8, 2001


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